

**REMARKS**

Reconsideration of this application is respectfully requested. Claims 20-37 are pending and at issue.

**Obviousness Rejection**

Claims 20-37 have been rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,943,590 (“Boegesoe”) in view of U.S. Patent No. 5,846,982 (“Audia”) and Schaller et. al., *J. Neuropsychiatry and Clin. Neurosciences*, 11(4):516, Fall 1999 (“Schaller”). The Examiner argues that Schaller provides the motivation to administer escitalopram (as taught by Boegesoe) to patients with ADHD as it would decrease their risk of depression. Audia purportedly teaches that ADHD can be treated with compounds that inhibit serotonin reuptake. The Examiner further contends that one of ordinary skill in the art would have had a reasonable expectation of “simultaneously and successfully treating depression in ADHD patients who are known to be at increased risk for major depression” (Office Action, page 5). Finally, the Examiner argues that Schaller describes “evidence of improvement in the condition of [an] ADHD patient” after treatment with a selective serotonin reuptake inhibitor (SSRI) (Office Action, p. 5).

Applicants traverse this rejection and respectfully request reconsideration.

Claims 20-37 are not obvious because, *inter alia*, Schaller teaches away from the presently claimed method by disclosing that ADHD must be treated separately from depression, and that an SSRI is not effective in treating ADHD.

Specifically, Schaller discloses the treatment of a patient suffering from ADHD, major depression, and an anxiety disorder (panic) (Schaller, page 516, col. 2). The patient was initially treated with sertraline, which is a selective serotonin reuptake inhibitor (“SSRI”). After receiving sertraline, the patient’s Beck Anxiety Inventory (“BAI”) score, a measure of generalized anxiety, improved from 28 to 20, but the patient’s panic attacks continued.

Clonazepam (a highly potent benzodiazepine, which is not an SSRI) was then administered to the patient, resulting in a BAI score of 4. On this treatment, the patient did not have panic attacks for two months.

Schaller states that “despite his improvement, the patient still met criteria for adult ADHD” (*see* Schaller, cols. 2 and 3). Thus, Schaller teaches that an SSRI (sertraline) did not effectively treat ADHD. The “improvement” referred to by Schaller was clearly in the patient’s anxiety level (i.e., lower BAI score), and not in ADHD. Additionally, the patient’s significant improvement in anxiety was noted only after administration of clonazepam, and not after the sertraline monotherapy. As to ADHD, the patient only improved when treated with both clonazepam and the stimulant methylphenidate (Ritalin®) (Schaller, p. 516, col. 3, ¶ 3).

Schaller concludes (p. 516, emphasis added):

[P]atients with such co-morbidities should have their [major depression] treated first, their anxiety disorder next, and finally be offered a non-combination, low potency stimulant for ADHD.

In other words, according to Schaller, depression and ADHD require separate treatments, suggesting that SSRIs (which are well known for their antidepressant activity) are not effective for treating ADHD. Furthermore, Schaller suggests treating ADHD with a stimulant, not an SSRI.

Reading Schaller in its entirety, a skilled artisan would not have been motivated to treat ADHD with an SSRI as the sole active ingredient, and would not have had a reasonable expectation that such treatment would be successful, because the patient treated in Schaller still met the criteria for adult ADHD after treatment with an SSRI. Contrary to the Examiner’s contention that attacking a single reference cannot show non-obviousness (*see* Office Action, p. 4), it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731 (Fed. Cir. 1983); *see also* MPEP 2145. Schaller teaches away from

treating ADHD with SSRIs because the patient's ADHD was only effectively treated with two non-SSRIs (i.e., clonazepam and methylphenidate).

Boegesoe and Audia fail to cure these defects. Boegesoe is silent with respect to the treatment of ADHD.

Audia does not disclose or suggest that *any* SSRI can be used to treat ADHD. Rather, Audia only teaches that the tetrahydropyridinyl- and piperidinyl-indoles and benzothiophenes described therein are useful in treating ADHD. *See* Audia at col. 1, lines 46-50, and col. 52, lines 1-3. Audia does not teach or suggest that SSRIs as a general class can be used to treat ADHD. At best, this reference merely discloses that compounds in the known class of SSRIs are generally used as antidepressants (*see* Audia, col. 1, lines 20-22). Therefore, one of ordinary skill in the art would not have had any motivation to combine Audia with Boegesoe, as escitalopram is not a tetrahydropyridinyl- or piperidinyl-indole or benzothiophene.

For the foregoing reasons, Boegesoe, Audia, and Schaller, alone or in combination, fail to render claims 20-37 obvious. Therefore, Applicants respectfully request withdrawal of this rejection.

### **Conclusion**

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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